

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-10, 12, 13, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the thread lead of the thread on the lead portion" in lines 7-8 along with "the thread lead of the thread on the tail portion" in lines 8-9. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the thread lead of the thread on the lead portion" in lines 6-7 along with "the thread lead of the thread on the tail portion" in line 7. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-10, 12-13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vrespa (US 5,593,410) in view of Bono et al. (US 6,129,730) in further view of Stevens et al. (US 7,811,312).

Regarding claims 1-3, 6-10, 12-13, and 17 Vrespa discloses a bone screw (figure 1) having a lead portion (24, figure 8) and a tail portion (23, figure 8), and an intermediate transition portion (22, figure 8), each of the lead portion and the tail portion comprising a root (32-24, figure 1) and a thread (26/28, figure 1), having a thread lead (figure 1) formed on the root, the thread on the lead portion having an approximately constant diameter along a significant portion of its length and tail portion having an approximately constant diameter along a significant portion of its length (figure 1), in which the diameter of the thread on the tail portion is greater than that of the thread on the lead portion (figure 1), and in which the thread lead of the thread on the lead portion is equal to the thread lead of the thread on the tail portion (figure 1), wherein the intermediate transition portion is configured between the threads of the lead portion and the tail portion, and is provided with a diameter that decreases gradually between the thread of the lead portion and the thread of the tail portion (figure 8), wherein the tail portion is provided with a socket end (16, figure 1), wherein the socket end of the tail portion is adapted to be, *i.e. capable*, flush with the surface of the bone or under the surface of the bone after the bone screw is fully inserted, and the thread on the lead portion of the screw is a multi-start thread (column 12, lines 55-58) in which the number of starts of the thread on the lead portion is equal to the ratio of the thread pitch of the thread on the tail portion to the thread pitch of the thread on the lead portion (column 12, lines 63-

67), and the thread on the tail portion of the screw is a single-start thread (column 12, line 43), in which the diameter of the root of the tail portion is greater than the diameter of the root of the lead portion (figure 1), and the diameter of the root of the tail portion is greater than the diameter of the root of the lead portion, and has a bore (30, figure 1, and 74, figure 4-5) extending through it along its length.

Vrespa et al. fail to expressly disclose the lead portion of the screw being a double-start thread and the tail portion of the screw being a single start thread and the pitch of the thread on the trail portion is equal to twice the thread pitch of the thread on the lead portion. Rather, Vrespa et al. teach that the threading on the lead portion of the screw is a multiple of the threading on the tail portion of the screw and having a respective difference in pitch between the respective portions of the screw equal to that multiple (see abstract, column 7, lines 54-67, column 12, lines 63-67).

Bono et al. teach the use of multi-lead/threaded lead portion and a tail portion of the screw having a single start threading. Bono in particular expressly teaches the use of double, triple, quadruple, or quintuple along with "others" (column 3, lines 61-67, column 4, lines 1-3) to provide a screw with the most desirable pull-out values inhibiting pull-out of the screw from cancellous bone (column 3, lines 61-67, column 4, lines 1-3). As such both Bono et al. and Vrespa both use a multi-start threading on the lead portion to remedy the same issue of obtaining the best purchase within the cancellous bone thereby inhibiting pull-out of the screw.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the lead screw portion of Vrespa to have a dual start threading instead of triple start threading as taught by Bono et al. to provide the screw with the most desirable pull-out values to inhibit pulling out of the screw from the cancellous bone region.

Vrespa et al. fail to disclose the claimed invention except that the threading on the trailing portion of the screw is interrupted/discontinuous with the leading portion instead of being continuous with the leading portion. Stevens et al. shows that discontinuous and continuous threading are equivalent structures known in the art (see column 7, lines 65-67 and column 8, lines 1-13). Therefore, because these two threading designs were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the interrupted/discontinuous threading of Vrespa for the continuous threading of Stevens et al.

Regarding claims 6-7, Vrespa in view of Bono in view of Stevens disclose the claimed invention except for the ratio of the diameter of the thread on the tail portion to that of the diameter of the thread on the lead portion is at least about 1.2, preferably at least about 1.5, and is not more than about 2.3, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the ratio of the diameter of the thread on the tail portion to that of the

diameter of the thread on the lead portion to be at least about 1.2, preferably at least about 1.5, and is not more than about 2.3, preferably not more than about 2.0; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 9-10, Vrespa in view of Bono in view of Stevens disclose the claimed invention except for the ratio of the diameter of the root on the tail portion to that of the diameter of the root on the lead portion is at least about 1.2, preferably at least about 1.4, and is not more than about 2.3, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the ratio of the diameter of the root on the tail portion to that of the diameter of the root on the lead portion to be at least about 1.2, preferably at least about 1.4, and is not more than about 2.3, preferably not more than about 2.0; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 12-13, Vrespa in view of Bono in view of Stevens disclose the claimed invention except for the ratio of the diameter of the thread aspect on the tail portion to that of the thread aspect ratio on the lead portion is at least about 1.2, preferably at least about 1.35, and is not more than about 2.2, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the thread aspect ratio of the tail portion with respect to

the lead portion to be at least about 1.2, preferably at least about 1.35, and is not more than about 2.2, preferably not more than about 2.0; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 17, Vrespa in view of Bono in view of Stevens discloses the claimed invention except for the root diameter of the lead portion is 4.5 mm and a root diameter of the tail portion is 6.5 mm.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the root diameter of the lead portion is 4.5 mm and a root diameter of the tail portion is 6.5 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vrespa (US 5,593,410) in view of Bono et al. (US 6,129,730) in view of Stevens et al. (US 7,811,312) in further view of Frigg et al. (US 5,180,382).

Vrespa in view of Bono in view of Stevens disclose the claimed invention except for the threading on the tail portion of the screw being a continuation of the one of the threads on the lead portion.

Frigg et al. disclose the threading on the leading portion (7, figure 1) with threading and a tail portion (6, figure 1) with threading which is a continuation of the

threading on the lead portion (figure 1) to permit continuous threading of the screw allowing for non-stop engagement within the bone/insertion body.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the device of Vrespa in view of Bono in view of Stevens to having continuous threading between the leading and trailing portions of the screw to permit continuous threading of the screw allowing for non-stop engagement within the bone/insertion body as taught by Frigg et al.

### ***Response to Arguments***

Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW LAWSON whose telephone number is (571)270-7375. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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